K020255

RICHARD WOLF
Medical Instruments Corporation

SEP 18 2002

353 Corporate Woods Parkway
Vernon Hills, IL 60061
Phone: 847-913-1113
Customer Service: 800-323-WOLF
www.richard-wolf.com

12.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **January 22, 2002**
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:

Trade name: RIWO NET Operating Control System	Model number: 5590.xxx 32115.xxx
Common name: Operating Control System RIWO NET, remote and voice control, CAN bus	Classification name: Endoscope and/or Accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K994231	1 SIEMENS Integrated Operating System (SIOS)	1 Siemens
2 K981993	2 EndoALPHA Integrated Endosurgery System	2 Olympus
3 K980787	3 HERMES Operating Room Control Center	3 Computer Motion
4	4 Operation Room Control OR1/ SCB PC	4 Karl Storz
5 K002328	5 SIOS-Interface for Light Projector, Camera, Insufflator	5 Richard Wolf

1 of 2

K020255

1.0 Description

The RIWO NET System 5590 provides central user control of an endoscopic operating system using either voice or remote control from the sterile area or touch screen monitor. The RIWO NET System controls various endoscopy devices by uniform graphical user interface, such as light sources, cameras, insufflators, video recorders, etc.

2.0 Intended Use

The RIWO NET SYSTEM 5590 is used for controlling an operating system by voice control, touch screen monitor or remote control unit in diagnostic and therapeutic endoscopy.

3.0 Technological Characteristics

The connected endoscopy devices communicate via CAN bus / RS-232 interface.
All the connected devices can always be controlled conventional with their buttons furthermore. When they are connected to the master RIWO NET System 5590, the RIWO NET controller recognized the new device automatically and after run-up period, the slave device can be used in the RIWO NET System.

The speech recognition is speaker independent. Various languages are available.

The complete RIWO NET System with endoscopy devices is placed in a mobile trolley.

4.0 Substantial Equivalence

The submitted devices are substantial equivalent to devices by Siemens, Olympus, Computer Motion, and Karl Storz. The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness.

5.0 Performance Data

The submitted devices are conforming to the international standards UL-2601-1, IEC60601-1 with A1and A2, IEC 60601-1-1 with A1, IEC 60601-1-2.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa

Robert L. Casarsa
Quality Assurance Manager

Date: Jan 22, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2002

Richard Wolf Medical Instruments Corporation
Robert L. Casarsa
Quality Assurance Manager
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K020255
Trade/Device Name: RIWO NET Operating Control System Model #5590
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: KOG
Dated: August 1, 2002
Received: August 2, 2002

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 INDICATIONS FOR USE

510(k) Number (if known): — K020255

Device Name: RIWO NET System 5590

Intended use: The RIWO NET SYSTEM 5590 is used for controlling an operating system by voice control, touch screen monitor or remote control unit in diagnostic and therapeutic endoscopy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020255

Prescription Use ✓ OR Over-The Counter _____
Per 21 CFR 801 109